November 5, 2014

<u>Via E-Mail and Certified Mail Number 70110110000154502154</u> Return Receipt Requested

Mr. John D. Hebert
Chief, Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Petition to Cancel Antimicrobial Cupron Enhanced EOS Surface

EPA Registration Number 84542-7

Dear John:

We write on behalf of our clients, Cupron, Inc. (Cupron) and its affiliate EOS Surfaces, LLC (EOS), to request that the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) reconsider the procedures it has adopted for Cupron's response to the November 2, 2012, and May 28, 2013, submissions by the Copper Development Association, Inc. (CDA). OPP has construed the CDA submissions as a petition to cancel the registration for the Antimicrobial Cupron Enhanced EOS Surface. The formal procedures OPP has adopted for Cupron's response to the CDA petition are not required or warranted by any established law or applicable policy. These formal procedures are inequitable, may create the misimpression that CDA's unfounded allegations are credible, and are materially prejudicial to Cupron's legal and commercial interests. Cupron is also requesting that OPP extend the date for Cupron's response to the CDA submissions by 45 days, or until January 8, 2015, to afford time for OPP to act on Cupron's request for revised procedures, to allow any revised procedures adopted by OPP to be in effect while Cupron prepares its response to the CDA submissions, and to accommodate scheduling issues during the holidays.

Cupron questions whether it was necessary for OPP to construe the CDA communications in the form they were submitted as a petition to cancel. OPP could have obtained the information needed to resolve this matter without adopting a construction that is profoundly prejudicial to Cupron's legal and commercial interests and in a way that is less amenable to an interpretation that the process lacks neutrality. Cupron acknowledges that construing the CDA submissions as a petition to cancel was one of many options available to OPP because CDA requested on November 2, 2012, that EPA "cancel or suspend the registration pending resolution of the efficacy and other issues detailed above," and on May 28, 2013, that

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EPA "reconsider the registration of the Cupron/EOS Surface product." While Cupron appreciates the opportunity to submit a detailed written response to CDA's allegations before OPP takes action on the CDA submissions, Cupron strenuously objects to OPP's decision to establish formal adjudicatory procedures for this process, and to treat any communications that Cupron might elect to make to OPP employees without serving CDA as "ex parte" communications.

Creating a formal process now neglects to acknowledge that CDA has for the past two years pursued a seemingly relentless campaign to eliminate Cupron as a competitor. Cupron was never advised by OPP or CDA of the existence of the first of the CDA submissions that OPP now construes as a "petition to cancel," and the creation of *ex parte* restrictions now does not change the unrestricted access to OPP staff that CDA has enjoyed since it made this first submission. The fact that EPA has now advised Cupron of the existence of these communications and provided an opportunity to respond does not mean that it is appropriate to adopt procedures that restrict Cupron's ability to make similar communications to OPP concerning the same matter. This is especially inappropriate given that this matter involves Cupron's own registrations and Cupron's proprietary information. The process OPP has created, apparently out of whole cloth, is prejudicial to Cupron and is contrary to EPA's duty under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(5) not to express a preference for one registration over another registration.

CDA effectively contends that EPA's previous action to register Cupron's EOS product was erroneous. Cupron is prepared vigorously to assist OPP in defending the legal and substantive basis for that prior action. While Cupron recognizes that CDA has a right to expect that EPA will ultimately take some action to dispose of its requests, Cupron is deeply concerned that CDA may attempt to characterize the formal procedures that OPP has adopted for this matter as an indication that OPP attaches some measure of credibility to the speculative and misleading assertions in the CDA submissions, rather than adopting a more neutral posture pending the response to these assertions by Cupron. Cupron believes that OPP adopted these formal procedures in good faith and did not intend that they be construed in this manner. Providing OPP with the benefit of the doubt will not, however, eliminate the profoundly prejudicial impression that these procedures create, nor will it restore much needed neutrality to an adjudicatory process that is now distorted in favor of CDA.

We can surmise two potential reasons why OPP may have elected to adopt formal procedures for this matter: (1) OPP may consider such procedures to be appropriate because it uses procedures of similar formality to resolve petitions to cancel a pesticide registration based on data compensation issues that are filed by another registrant under 40 C.F.R. Section 152.99; and (2) OPP may consider it helpful to constrain unilateral communications by Cupron in

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assembling a satisfactory administrative record to support OPP's ultimate decision on the CDA submissions.

With respect to the first reason, Cupron respectfully suggests that any analogy to petitions to cancel filed under 40 C.F.R. Section 152.99 is spurious. As you know, decisions on petitions of this type are made by the Office of General Counsel (OGC), and EPA has asserted the right to grant such a petition in some instances by cancelling the affected registration without any further hearing. Given this situation, EPA has considered it advisable to adopt restrictions on *ex parte* communications with OGC that are analogous to the restrictions applicable in formal adjudications under the Administrative Procedure Act, 5 U.S.C. Section 556(d).

The instant petition to cancel is not analogous. CDA has already been in regular unilateral communication with OPP concerning this petition for a period of nearly two years without any prior notice to Cupron. The policy concerning communications by Cupron should be no more restrictive, particularly given that this matter addresses Cupron's own registrations, involving Cupron's proprietary information, and not data compensation issues. We recognize that a petition to cancel a registration that is implicitly based on the "unreasonable adverse effects" standard for cancellation in FIFRA Section 6(b), 7 U.S.C. Section 136d(b), and was submitted by another registrant is novel and may even be unprecedented, but there is no valid legal reason to constrain communications concerning such a petition between OPP and the affected registrant. In this instance, the decision maker is OPP rather than OGC and no summary cancellation order would be legally permissible.

With respect to the second reason, Cupron agrees that OPP has a valid interest in assuring the viability and accuracy of the administrative record that will support its ultimate decision concerning the CDA submissions. Nevertheless, OPP can readily achieve this objective by assuring that all substantive communications with Cupron that include any information or argument considered by OPP in making its decision are included in the administrative record. There is no need to adopt a formal constraint on communications between OPP and Cupron, which clearly did not apply under the rules that governed communications between OPP and CDA over the preceding two years. Cupron does not desire to make any such communication with OPP in confidence, and OPP is free to document such communications to the extent it deems such documentation necessary to assure a complete and accurate administrative record.

Accordingly, Cupron is specifically requesting that OPP revise the formal procedures set forth in its September 25, 2014, letter. Cupron respectfully requests that OPP respond to this request by November 10, 2014, which is 14 days before the due date for the

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⁴⁰ C.F.R. § 152.99(c)(2).



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Cupron response of November 24, 2014, established by the September 25, 2014, letter. In addition, Cupron respectfully requests that OPP extend the date for Cupron's response to the CDA submissions by 45 days, or until January 8, 2015, to afford time for OPP to act on Cupron's request for revised procedures, to allow any revised procedures that are adopted by OPP to be in effect while Cupron prepares its response to the CDA submissions, and to accommodate scheduling issues during the holiday period. Cupron requests that OPP grant this extension immediately, but in no event later than November 10, 2014.

Thank you for your prompt consideration of the requests made in this letter.

Sincerely,

Lynn L. Bergeson Timothy D. Backstrom

cc: Mr. Andrew G. Kireta, Sr., President and CEO, Copper Development Association, Inc. (via e-mail and certified mail 70110110000154502161, return receipt requested)
Joseph J. Green, Esquire, Kelley Drye & Warren LLP (via e-mail)
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